Claims 1-10 and 46-53 were rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner states that Claims 1 and 9 are vague and indefinite because it is unclear how the chemical and physical properties of the polymer and the solvent must be related to enable the invention to operate. The Examiner further states that the claim is unduly broad because all biocompatible solvents will not dissipate from the implant and therefore the claim lacks sufficient recitation of the chemical and physical properties to enable the functional step C. Additionally, the Examiner states that the claim is unduly broad because some nonreactive polymers exist which will not form solid implants in the body.

Claim 1 has been amended to better show that the polymer is a water-insoluble polymer and the solvent is a water-soluble solvent. Therefore, when the solution is placed within the body, the solvent diffuses into the aqueous body fluids and the water from the body fluids diffuses into the polymer solution where it precipitates the water insoluble polymer. The resulting precipitate forms the implant. Support for this recitation is found at page 11, line 6 through page 14, line 23 of the specification, which provides a definition of the terms water-insoluble polymer and water-soluble solvent as used herein, and a more detailed description of the functions of the elements of the

invention. Applicants believe that Claim 1, as amended, now conforms to the statute.

The Examiner has noted that Claim 2 contains water-soluble polymers which will not form solid implants. Applicant has amended Claim 2 by eliminating polyvinylpyrrolidone, polyethylene glycol, and polyhydroxycellulose from the group. Applicants believe that Claim 2, as amended, in light of the amendment to Claim 1 and the specification, now conforms to the statute.

Claims 2-10 were rejected as vague and indefinite because the Markush group was improperly expressed. Applicants have amended Claims 2, 3, 4, 5 and 10 to include the expression "consisting of". Therefore, Claims 2-10, as amended, are felt to conform to the statute.

Claim 7 was rejected as vague and indefinite because it is unclear what the term "and/or" implies. Applicants have amended Claim 7 to read "by diffusion, erosion or a combination of diffusion and erosion". Therefore, Claim 7, as amended, is felt to conform to the statute.

Claims 1, 7, 8, 46 and 52 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent No. 3,219,527 to Gurney. However, Claim 1, as amended further recites the step

of "dissolving a non-reactive, water-insoluble polymer in a biocompatible, water-soluble solvent to form a liquid". Gurney, on the other hand, teaches mixing zinc oxide plus eugenol to form a composition which is biocompatible, but which is certainly not biodegradable. When liquid eugenol is mixed in the right proportions with zinc oxide, the eugenol monomer in the mixture simultaneously polymerizes and cross-links with bivalent zinc ions to form a solid. Because eugenol is a reactive liquid monomer which becomes a polymer only when the zinc is added (see Col. 4, lines 61-65), it should not, in any way, be compared to the non-reactive solvents of the present invention. Likewise, the zinc oxide is an inorganic salt and not a water-insoluble polymer as required by the present invention.

Furthermore, all of the polymers used in the present invention are preexisting before they are dissolved in the solvent. They are not liquid monomers which polymerize <u>in-situ</u> to form solvent polymers. On the other hand, Gurney's material is a liquid monomer, eugenol, whose polymerization is catalyzed by the zinc oxide. As a result, Gurney has both a solid and a liquid phase which must be kept separate until use and which, when mixed, require time to solidify. The present invention, because it has preformed polymers dissolved in a water-soluble solvent, forms a solid implant immediately as a water-insoluble polymer precipitates when the material comes in contact with water or body fluids.

Further differences also exist between Gurney and the present invention. For example, Gurney's total material cannot be delivered with a syringe to the patient, only the liquid portion. Some other procedure would be required to position the material within a periodontal pocket. In the case of the present invention, the total material is syringable as a liquid in one step. Furthermore, Gurney's material is a periodontal pack or dressing which is placed over gingival tissue in the mouth and is not designed to be placed below the gum line into periodontal pockets as is the present invention. Also, the Gurney material is not designed to be fabricated or used as a drug delivery system. Rather, Gurney merely incorporates agents to keep the pack or material itself bacteriostatic and anti-fungal. Unlike the present invention, Gurney does not incorporate the drug into his material to effect a biological action in the tissue itself.

Therefore, Claims 1, 7, 8, 46 and 52 are felt to distinguish patentably from Gurney.

Claims 1, 2, 6, 7, and 46 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by U.S. Patent No. 4,570,629 to Widra. However, Widra describes a material that is very different from that of the present application. Widra teaches the use of two water-soluble polymers that form an insoluble polymer salt when they are mixed together. One polymer is an anionic material, and the other is a cationic material. In these

forms, both are water-soluble. But when they are mixed, the cationic material complexes with the anionic material to form a water-insoluble salt. Widra indicates that this precipitation is due to salt formation plus some chemical bonding and cross-linking. (See Col. 4, lines 20-38). Thus, the polymers of Widra are clearly reactive, while the single polymer claimed in the present invention is nonreactive. The present invention therefore relies on materials that are already formed and does not need a chemical reaction for a solid implant to form. Also, Widra requires at least two polymers while the present invention can rely on one.

Furthermore, the polymers of the present invention are water-insoluble and the addition of water causes them to precipitate from a water-soluble solvent. On the other hand, Widra's solvent for his water-soluble polymers is water itself, and there is no teaching of water-soluble solvents in Widra.

Furthermore, Widra relies on the use of two separate solutions and mixes these to form a solid material regardless of whether in the body or in the presence of water. The material of the present invention is a single solution which forms a solid only upon contact with body fluids or water.

Furthermore, the present invention forms a solid implant which cannot be easily deformed after complete

solidification. Widra describes his precipitated poly-salt as a gel, paste, or putty when in contact with moisture, and further states that only when the salt is dried does it become a true solid. (See Col. 4, lines 39-52). Such drying is not possible inside the body, which is an aqueous environment. Therefore, Widra does not provide a solid implant as can be had from the present invention and clearly does not teach forming a solid in a body. Therefore, Claims 1, 2, 6, 7, and 46 are felt to distinguish patentability from Widra.

Claims 3-5, 9, 10 and 46-53 were rejected under 35 U.S.C. §103 as being unpatentable over Widra in view of U.S. Patent No. 3,887,699 to Yolles. The Examiner states that Widra discloses the instant invention except for the specific polymers, solvents and drugs of the claims, and that Yolles exemplifies that polylactides are commonly used as biodegradable drug delivery devices. In addition, the Examiner states that Yolles discloses a wide variety of drugs which can be employed in the invention. The Examiner concludes that it would be obvious to one of ordinary skills in the art to use the biodegradable polymers of Yolles in the Widra device because Widra discloses the desirable characteristics of the device in terms of malleability, drug release and bioerodibility. Similarly, the Examiner states that it is an obvious design choice to incorporate any drug into the Widra device to correspond with the

desired therapeutic effect. Applicants respectfully traverse this rejection.

Claims 3-5, 9, 10, 46-53 contain the limitations of amended Claim 1. Claim 1, as amended, is believed to be patentably distinguishable from Widra for the reasons set forth above. The substitution of polylactide for the polymer of Widra would do nothing to change the fact of such patentability, and therefore it is believed that, because of such dependency, Claims 3-5, 9, 10, and 46-53 should also be patentable over the suggested combination.

Also, the combination of the cited references as proposed by the Examiner would have to be sufficiently pertinent to the particular problem faced by the applicants as to reasonably suggest applicants' claimed solution to those skilled in the art. This is not the case here. Widra discloses a wound dressing which is flexible and elastic in the presence of moisture. Only upon drying is a solid implant formed. Therefore, in order to form a solid implant using the Widra materials, the water-soluble polymers must first be mixed outside of the body and the mixture then inserted into the patient in its solid form. Therefore, Widra clearly presents problems in forming implants in the aqueous environment of the body, such as in a periodontal pocket. Yolles describes the controlled delivery of drugs from polymeric systems with methods to

fabricate and control the drug release, and mentions biodegradable polymers such as polylactides and polyglycides. However, Yolles' delivery systems are all solid materials formed outside the body and then implanted or injected as microspheres or small particles. Yolles does not describe or anticipate the injection of a polymer dissolved in a solvent to form a solid implant as found in the present invention. Therefore, a person skilled in the art who is looking for a solution to the problem of incapability of forming a solid implant in the aqueous environment of a periodontal pocket, as exhibited by Widra, would hardly be disposed, on any objective basis, to consider a reference like Yolles, which not only is unconcerned with forming implants inside of a body but which shows absolutely no recognition of such problem - let alone any method that would avoid or solve it. Therefore, applicants respectfully submit that it would not be proper to combine the references in the manner suggested by the Examiner.

Furthermore, even if it were proper to so combine the references under §103, the resulting structure would not meet the terms of Claims 3-5, 9, 10, and 46-53. The claims all relate to dissolving a non-reactive polymer in a biocompatible, water-soluble solvent to form a liquid, placing the liquid within a body, and allowing the solvent to dissipate to produce an implant <u>in-situ</u>. By contrast, Widra relies upon water as a solvent, and does not teach in any way the use of a water-soluble solvent.

Therefore, the combination which would result from substituting the polylactide of Yolles for either of the water-soluble polymers required by Widra, as proposed by the Examiner, would still lack the ability to form an injectable liquid, and therefore could not provide the ability to form a solid implant in-situ. It follows that the subject matter of Claims 3-5, 9, 10, and 46-53 would not have been obvious of Widra and Yolles at the time the invention was made.

Applicant notes that it appears that no action has been taken on Claim 29, which has not been withdrawn from this application.

An extension of 1 month has been requested, and the appropriate fee provided.

On the basis of the above amendments and remarks, reconsideration and allowance of the application is believed to be warranted.

Respectfully submitted,

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